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Docket No.: 58686US001 (Formerly 2005)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: LAWRENCE XAVIER WEBB, M.D.  
Application No.: 09/553,683 Group Art Unit: 3737  
Filed: April 21, 2000 Examiner: E.M. Mercader  
Title: SURGICAL TARGETING SYSTEM

**BRIEF ON APPEAL**

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October 11, 2005	<i>Nancy M. Lambert</i>
Date	Signed by: Nancy M. Lambert

Dear Sir:

This is an appeal from the Office Action mailed on March 8, 2005, finally rejecting claims 30, 32, 34-57, 59, and 61-75.

A Notice of Appeal in this application was mailed on July 8, 2005, and was received in the USPTO on July 8, 2005.

The fee required under 37 CFR § 41.20(b)(2) for filing an appeal brief should be charged to Deposit Account No. 13-3723.

Appellants request the opportunity for a personal appearance before the Board of Appeals to argue the issues of this appeal. The fee for the personal appearance will be timely paid upon receipt of the Examiner's Answer.

Application No.: 09/553,683

Docket No.: 58686US03  
1 1 2005**REAL PARTY IN INTEREST**

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

**RELATED APPEALS AND INTERFERENCES**

Appellants are unaware of any related appeals or interferences.

**STATUS OF CLAIMS**

Claims 30, 32, 34-57, 59, and 61-75 are pending, stand rejected, and form the basis of this Appeal. Claims 28-29 are allowed.

**STATUS OF AMENDMENTS**

No amendments have been filed after the final rejection.

**SUMMARY OF CLAIMED SUBJECT MATTER**

Claims 30, 32, 34-46, 47-51, and 68-75 generally concern a sterile surgical drape comprising a radio-lucent sheet, an adhesive on a major surface of the radio-lucent sheet and

(1) a radio-opaque pattern with a plurality of intersections on the sterile surgical drape [Page 18, lines 15-26; page 21-lines 15-23; page 38, line 19 to page 39, line 4; Figures 1-32];

(2) a plurality of unique radio-opaque labels located at the intersections on the sterile surgical drape [Page 19, lines 11-27; page 38, line 19 to page 39, line 4; Figures 1-8, 10, 12, 13-15, 32] .

Claims 53-56 and 67 generally concern a sterile surgical drape comprising a radio-lucent sheet comprising a central cutout and a slit extending outward from the central cutout [Page 32, lines 23-32; Figures 31-36]; adhesive on a major surface of the radio-lucent sheet;

(1) a radio-opaque pattern with a plurality of intersections on the sterile surgical drape [Page 18, lines 15-26; page 21-lines 15-23; page 38, line 19 to page 39, line 4; Figures 1-32];

(2) a plurality of unique radio-opaque labels located at the intersections on the sterile surgical drape [Page 19, lines 11-27; page 38, line 19 to page 39, line 4; Figures 1-8, 10, 12, 13-15, 32] .

Claims 57, 59, and 61-66 generally concern a medical imaging method comprising adhering various embodiments of the sterile surgical drapes described above to a patient; and directing imaging radiation at the patient and through the sterile surgical drape, wherein an image is obtained that includes a pattern image corresponding to the radio-opaque pattern on the sterile surgical drape, the pattern image comprising a plurality of label images corresponding to the radio-opaque labels on the sterile surgical drape.

#### **GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

##### **First Ground of Rejection**

Claims 30, 32, 34-38, 41-43, 47-49, 53-61, 67 and 71-75 stand rejected under 35 USC § 103(a) as purportedly unpatentable over the combined teachings of U.S. Patent No. 4,899,762 (Muller), in view of U.S. Patent No. 5,052,035 (Krupnick).

##### **Second Ground of Rejection**

Claims 39-40, 44-46, 50-52, 52-57, 59, 61-66, and 68-70 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,899,762 (Muller) in view of U.S. Patent No. 5,052,035 (Krupnick), and U.S. Patent No. 5,260,985 (Mosby).

#### **ARGUMENT**

##### **First Ground of Rejection**

The Examiner rejected claims 30, 32, 34-38, 41-43, 47-49, 53-61, 67 and 71-75 under 35 U.S.C. § 103(a) as being unpatentable over Muller in view of Krupnick. Applicant notes that claims 58 and 60 have been previously canceled, rendering their rejection moot.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. In re Fine, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). To establish a *prima facie* case of obviousness, three basic criteria must be met:

- 1) there must be some suggestion or motivation, either in the reference or the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings;
- 2) there must be a reasonable expectation of success;
- 3) the prior art reference, or combined references must teach or suggest all the claim limitations.

*See Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F. 3d 1376, 58 USPQ2d 1286 (Fed. Cir. 2001); M.P.E.P. § 2142 (citations omitted).

The independent claims 30 and 57 recited surgical drapes that are sterile and include "a plurality of uniquely labeled intersections" that are "in the interior of the radio-opaque pattern." None of the cited references disclose such a construction.

The labels of Muller are located only at the periphery of the drape. Nor does Krupnick disclose unique labels located within the interior of the pattern formed thereon. Significantly, neither Muller or Krupnick teach or suggest that either individual intersections be labeled, or that labels are located within the interior of the radio-opaque pattern.

Further, neither Muller or Krupnick disclose a sterile drape or sheet with unique labels. Muller discloses a combination surgical drape and dressing for apposition after surgery for sewing up a wound, and then remaining in location after surgery. Krupnick focuses on identifying locations on the patient's body with a "marking sheet temporarily applied in order to place markings on the patient's body, then removed prior to surgery. Krupnick fails to disclose either a sterile drape or an incise drape. As discussed in Applicants' Specification on page 7, the device in Krupnick is non-sterile, and requires removal after marking the location on the patient. If further marking was required, the use of a Krupnick device would compromise the sterile field.

The Examiner states that the addition of a sterile limitation to the surgical drape is inherent in any medical procedure in order to avoid contamination of the surgical field. However, the Examiner points to no disclosure in either Muller or Krupnick disclosure to support this conclusion. Applicants submit that the Examiner's conclusion can only be reached in hindsight using Applicants' disclosure. *In re Kotzab*, 208 F. 3d 1352 (Fed. Cir. 2000). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicants' disclosure. See M.P.E.P §706.02(j).

Thus, the proposed combination of Muller and Krupnick fail to teach or suggest all the limitations of independent claims and their respective dependent claims as required for a proper *prima facie* case of obviousness.

With respect to independent claims 47 and 61, neither Muller or Krupnick teach or suggest that "every intersection of the plurality of intersections comprises one of the radio-opaque labels such that every intersection of the plurality of intersections comprises one of the labeled intersections of the plurality of labeled intersections" as is recited. Rather, the cited references teach patterns in which the labels are limited to the edges or perimeters of the patterns. As a result, labels are not found at every intersection as recited in independent claims 47 and 61 and dependent claims 48 and 49.

As for the comments related to "criticality" of the labeled intersections found on page 2 of the Office Action, Applicants note that, in fact, the advantages have been identified for including unique labels within the interior of the radio-opaque pattern on surgical drapes in the Specification. See, e.g., p. 19, lines 11-29. As indicated, accurate identification of the surgical site may be facilitated by including labels at intersections within the interior of the pattern. Actual physical labels located at intersections within the interior of the pattern do not provide the advantages of the labeled intersections and, therefore, cannot be "functional equivalents" to imaginary labels that do not physically exist, but that must, instead, be derived from labels at the edges of a pattern.

With respect to independent claim 53, Applicants note that neither Muller or Krupnick disclose or suggest (alone or in combination) a sterile surgical drape that includes "a central cutout and a slit extending outward from the central cutout" as recited. It is asserted that Krupnick discloses "a cutout through the grid lines to effectuate a biopsy (see Figure 2 and see col. 5, lines 17-31)." Applicant disagrees.

First, the features disclosed by Krupnick are limited to die cut lines in the sheet, not a cutout in the sheet as recited in claim 53. Krupnick does not disclose that any material is removed by the die cutting. Rather, the corners at the die cut intersection must be raised to permit marking of the underlying surgical site. Second, Krupnick does not disclose a line extending outward from a cutout because no cutout itself is disclosed. The Examiner considers a biopsy needle as "a cutout." There is no teaching or disclosure in the references to suggest that insertion of a biopsy needle could provide

for removal of sheet material to form a cutout or a line extending outward from the cutout.

For at least the above reasons, Applicant respectfully submits that claims 30, 32, 34-38, 41-43, 47-49, 53-61, 67 and 71-75 are not *prima facie* obvious over Muller in view of Krupnick.

### **Second Ground of Rejection**

The Examiner rejected claims 39-40, 44-46, 50-52, 52-57, 59, 61-66, and 68-70 under 35 U.S.C. § 103(a) as being unpatentable over Muller in view of Krupnick, and U.S. Patent No. 5,260,985 (Mosby). Applicant submits that claims 39-40, 44-46, 50-52, and 62-66 are not *prima facie* obvious over Muller in view of Krupnick and Mosby for at least the reason that the combination of Muller, Krupnick and Mosby does not teach all of the features recited in those claims.

All of claims 39-40, 44-46, and 50-52 depend from one of the independent claims discussed above with respect to the rejection based on only Muller and Krupnick. The addition of Mosby does not address any of the deficiencies of Muller and Krupnick as applied to those independent claims. For that reason alone, Applicant respectfully submits that claims 39-40, 44-46, and 50-52 are patentable over the combination of Muller in view of Krupnick and Mosby.

With respect to dependent claim 50, Applicant further notes Mosby does not disclose or suggest "a slit extending outward from the central cutout" as recited in claim 49, from which claim 50 depends.

With respect to dependent claims 45, 46, 51, 52, Applicant notes that the combination of Muller in view of Krupnick and Mosby does not disclose or suggest "a cylindrical portion adapted to fit over a finger" as recited in claims 45 and 51. Nor does the combination of Muller in view of Krupnick and Mosby teach or suggest "a hemispherical end portion located at one end of the cylindrical portion" as recited in claims 46 and 52.

The rejection of claims 45, 46, 51 and 52 is premised on the assertion that the cited portions of Mosby teach "the use of radio-opaque circles and utilization of pliable material for use on breast procedures or on body parts resembling cylindrical or conical configurations such as a finger." A careful review of Mosby (including the portions cited in support of this rejection), however, reveals that Mosby does not disclose or

suggest that the adhesive sheet may be used on a finger. As a result, the rejection of claims 45, 46, 51, and 52 is not supported by the combination of Muller in view of Krupnick and Mosby.

With respect to independent method claims 62 and 64, Applicant submits that the combination of Muller in view of Krupnick and Mosby does not teach or suggest "a plurality of unique radio-opaque labels disposed over the surgical drape, wherein each radio-opaque label of the plurality of radio-opaque labels is located at one intersection of the plurality of intersections in the radio-opaque pattern to provide a plurality of labeled intersections disposed over the surgical drape" as recited in each of these independent claims. One example of such an arrangement is depicted in, e.g., Figure 1 of the present application.

In contrast, Muller and Krupnick both teach that labels are limited to the perimeter of the patterns formed on the sheets. For example, in Figure 1 of both Muller and Krupnick illustrate this point, i.e., all of the labels are located at the perimeters of the radio-opaque patterns. Significantly, neither Muller or Krupnick teach or suggest that individual intersections be labeled. Mosby does not teach any labels on the sheet material.

As a result, the combination of Muller in view of Krupnick and Mosby does not support a *prima facie* case of obviousness with respect to independent claims 62 and 64 or their respective dependent claims 63, 65, and 66.

With respect to independent claim 62, Applicant notes that the combination of Muller in view of Krupnick and Mosby also do not teach or suggest "a central cutout and a slit extending outward from the central cutout" as recited in claim 62.

With respect to independent claim 64, the combination of Muller in view of Krupnick and Mosby does not teach or suggest "unrolling a cylindrical portion of the surgical drape onto an extremity, finger or other appendage of the patient" as recited. In fact, the Office Action is silent as to where these actions are taught in the cited references or how they are rendered obvious in view of the cited references.

In view of the above, Applicant respectfully submits that claims 39-40, 44-46, 50-52, 52-57, 59, 61-66, and 68-70 are not *prima facie* obvious over Muller in view of Krupnick and Mosby.

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**CONCLUSION**

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application. Appellants respectfully request that the Examiner be reversed on all counts.

Respectfully submitted,

October 11, 2005  
Date

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**CLAIMS APPENDIX**

1 – 27 (Canceled)

28. (Allowed) A method for correlating the buttock with the femoral canal of the femur of a body, said method comprising the steps of:

applying a radio-transparent drape having at least two indicia each comprising a radio-opaque longitudinal axis to the leg of the body such that a first portion of the drape extends in an anterior-posterior plane relative to the body, said applying step further providing for a second portion of the drape to extend laterally relative to the body, said applying step providing further for each of the indicia to be contained in respective first and second portions of the drape, said applying step providing further for each of the indicia to be longitudinally and centrally aligned relative to the leg;

directing imaging radiation through said drape such that a radiographic image of said body and indicia is formed on a medium;

comparing, by viewing the radiographic image, the relative positions of each of the indicia relative to the longitudinal axis of the femoral canal;

translating the drape, as required, relative to the leg such that one of the indicia is contained in an anterior-posterior plane which coincides with the longitudinal axis of the femoral canal, and such that the other of the indicia is contained in a lateral plane which coincides with the longitudinal axis of the femoral canal; and

locating the intersection of the indicia on the buttock, the intersection of the indicia defining a start point for a reference axis which, when intersecting said start point and parallel to the indicia, coincides with the longitudinal axis of the femoral canal.

29. (Allowed) A method as set forth in claim 28 and further comprising the steps of:

positioning a longitudinal nail relative to the leg such that a pointed end of the nail is adjacent to the start point on the buttock;

orienting the nail relative to the leg such that the longitudinal axis of the nail coincides with the reference axis;

inserting the nail through the tissue of the leg such that the longitudinal axis of the nail coincides with the reference axis, said inserting step being initiated by puncturing the outer surface of the leg at the start point with the pointed end of the nail;

inserting the nail further through the tissue such that the longitudinal axis of the nail continues to coincide with the reference axis, and such that the pointed end of the nail punctures the proximal end of the femoral canal; and

inserting the nail further into the femoral canal such that the longitudinal axis of the nail continues to coincide with the reference axis.

30. (Previously presented) A sterile surgical drape comprising:

a radio-lucent sheet;

adhesive on a major surface of the radio-lucent sheet;

a radio-opaque pattern on the sterile surgical drape, wherein the radio-opaque pattern comprises a perimeter, an interior within the perimeter, and a plurality of intersections distributed within the interior of the radio-opaque pattern; and

a plurality of unique radio-opaque labels on the sterile surgical drape, wherein each radio-opaque label of the plurality of unique radio-opaque labels is located at one intersection of the plurality of intersections in the radio-opaque pattern, and wherein a plurality of uniquely labeled intersections are provided in the interior of the radio-opaque pattern on the sterile surgical drape.

31. (Canceled)

32. (Previously Presented) A surgical drape according to claim 30, wherein every intersection of the plurality of intersections comprises one of the radio-opaque labels such that one radio-opaque label of the plurality of unique radio-opaque labels is located at every intersection of the plurality of intersections.

33. (Canceled)

34. (Previously Presented) A surgical drape according to claim 30, wherein the radio-opaque pattern comprises a first set of lines and a second set of intersecting lines,

wherein the first set of lines and the second set of intersecting lines form the plurality of uniquely labeled intersections.

35. (Previously Presented) A surgical drape according to claim 34, wherein some intersections of the plurality of intersections do not include one of the unique radio-opaque labels.

36. (Previously Presented) A surgical drape according to claim 34, the second set of intersecting lines is oriented at right angles to the first set of lines.

37. (Previously Presented) A surgical drape according to claim 34, wherein the lines in the first set of lines are located at regular intervals.

38. (Previously Presented) A surgical drape according to claim 34, wherein the lines in the first set of lines are straight lines.

39. (Previously Presented) A surgical drape according to claim 34, wherein the lines in the first set of lines are concentric circles.

40. (Previously Presented) A surgical drape according to claim 39, wherein the lines in the second set of lines are radially oriented with respect to the concentric circles of the first set of lines.

41. (Previously Presented) A surgical drape according to claim 30, wherein the radio-opaque pattern comprises lines of different shapes.

42. (Previously Presented) A surgical drape according to claim 30, wherein the radio-opaque pattern comprises a plurality of quadrants defined by four labeled intersections of the plurality of labeled intersections.

43. (Previously Presented) A surgical drape according to claim 30, wherein the sheet comprises a central cutout and a slit extending outward from the central cutout.

44. (Previously Presented) A surgical drape according to claim 43, wherein the radio-opaque pattern comprises a set of concentric circles centered about the central cutout.

45. (Previously Presented) A surgical drape according to claim 30, wherein the sheet comprises a cylindrical portion adapted to fit over a finger.

46. (Previously Presented) A surgical drape according to claim 45, wherein the sheet further comprises a hemispherical end portion located at one end of the cylindrical portion.

47. (Previously Presented) A sterile surgical drape comprising:  
a radio-lucent sheet;  
adhesive on a major surface of the radio-lucent sheet;  
a radio-opaque pattern on the sterile surgical drape, wherein the radio-opaque pattern comprises a first set of lines and a second set of intersecting lines, wherein the first set of lines and the second set of intersecting lines form a plurality of intersections;  
and

a plurality of radio-opaque labels on the sterile surgical drape, wherein each radio-opaque label of the plurality of radio-opaque labels is located at one intersection of the plurality of intersections in the radio-opaque pattern to provide a plurality of labeled intersections on the sterile surgical drape;

wherein every intersection of the plurality of intersections comprises one of the radio-opaque labels such that every intersection of the plurality of intersections comprises one of the labeled intersections of the plurality of labeled intersections; and

wherein the radio-opaque label at each labeled intersection of the plurality of labeled intersections is unique.

48. (Previously Presented) A surgical drape according to claim 47, wherein the radio-opaque pattern comprises a plurality of quadrants defined by four labeled intersections of the plurality of labeled intersections.

49. (Previously Presented) A surgical drape according to claim 47, wherein the sheet comprises a central cutout and a slit extending outward from the central cutout.

50. (Previously Presented) A surgical drape according to claim 49, wherein the radio-opaque pattern comprises a set of concentric circles centered about the central cutout.

51. (Previously Presented) A surgical drape according to claim 47, wherein the sheet comprises a cylindrical portion adapted to fit over a finger or other appendage.

52. (Previously Presented) A surgical drape according to claim 51, wherein the sheet further comprises a hemispherical end portion located at one end of the cylindrical portion.

53. (Previously Presented) A sterile surgical drape comprising:  
a radio-lucent sheet comprising a central cutout and a slit extending outward from the central cutout;  
adhesive on a major surface of the radio-lucent sheet;  
a radio-opaque pattern on the sterile surgical drape, wherein the radio-opaque pattern comprises a plurality of intersections, wherein the radio-opaque pattern comprises a first set of lines and a second set of intersecting lines, wherein the first set of lines and the second set of intersecting lines form a plurality of intersections and further wherein the lines in the first set of lines are concentric circles and the lines in the second set of lines are radially oriented with respect to the concentric circles of the first set of lines; and  
a plurality of radio-opaque labels on the sterile surgical drape, wherein each radio-opaque label of the plurality of radio-opaque labels is located at one intersection of the plurality of intersections in the radio-opaque pattern to provide a plurality of labeled intersections on the sterile surgical drape.

54. (Previously Presented) A surgical drape according to claim 53, wherein the radio-opaque label at each labeled intersection of the plurality of labeled intersections is unique.

55. (Previously Presented) A surgical drape according to claim 53, wherein every intersection of the plurality of intersections comprises one of the radio-opaque labels such that every intersection of the plurality of intersections comprises one of the labeled intersections of the plurality of labeled intersections.

56. (Previously Presented) A surgical drape according to claim 55, wherein the radio-opaque label at each labeled intersection of the plurality of labeled intersections is unique.

57. (Previously Presented) A medical imaging method comprising:  
adhering a sterile surgical drape to a patient, wherein the sterile surgical drape comprises a radio-lucent sheet and a radio-opaque pattern on the sterile surgical drape, wherein the radio-opaque pattern comprises a perimeter, an interior within the perimeter, and a plurality of intersections distributed within the interior of the radio-opaque pattern, and a plurality of unique radio-opaque labels on the sterile surgical drape, wherein each radio-opaque label of the plurality of unique opaque labels is located at one intersection of the plurality of intersections in the radio-opaque pattern, and wherein a plurality of uniquely labeled intersections are provided in the interior of the radio-opaque pattern on the sterile surgical drape; and

directing imaging radiation at the patient and through the sterile surgical drape, wherein an image is obtained that includes a pattern image corresponding to the radio-opaque pattern on the sterile surgical drape, the pattern image comprising a plurality of label images corresponding to the radio-opaque labels on the sterile surgical drape.

58. (Cancelled)

59. (Previously Presented) A method according to claim 57, wherein every intersection of the plurality of intersections comprises one of the radio-opaque labels such that one radio-opaque label of the plurality of unique radio-opaque labels is located at every intersection of the plurality of intersections.

60. (Cancelled)

61. (Previously Presented) A method of medical imaging comprising:  
adhering a sterile surgical drape to a patient, wherein the sterile surgical drape comprises:

a radio-lucent sheet;

a radio-opaque pattern on the sterile surgical drape, wherein the radio-opaque pattern comprises a first set of lines and a second set of intersecting lines, wherein the first set of lines and the second set of intersecting lines form a plurality of intersections, and a plurality of radio-opaque labels on the sterile surgical drape;

wherein each radio-opaque label of the plurality of radio-opaque labels is located at one intersection of the plurality of intersections in the radio-opaque pattern to provide a plurality of labeled intersections on the sterile surgical drape;

wherein every intersection of the plurality of intersections comprises one of the radio-opaque labels such that every intersection of the plurality of intersections comprises one of the labeled intersections of the plurality of labeled intersections; and

wherein the radio-opaque label at each labeled intersection of the plurality of labeled intersections is unique;

directing imaging radiation at the patient and through the sterile surgical drape, wherein an image is obtained that includes a pattern image corresponding to the radio-opaque pattern on the sterile surgical drape, the pattern image comprising a plurality of label images corresponding to the radio-opaque labels on the sterile surgical drape.

62. (Previously Presented) A method of medical imaging comprising:  
adhering a sterile surgical drape to a patient, wherein the sterile surgical drape comprises:

a radio-lucent sheet comprising a central cutout and a slit extending outward from the central cutout;

a radio-opaque pattern on the sterile surgical drape, wherein the radio-opaque pattern comprises a first set of lines and a second set of intersecting lines, wherein the first set of lines and the second set of

intersecting lines form a plurality of intersections and further wherein the lines in the first set of lines are concentric circles and the lines in the second set of lines are radially oriented with respect to the concentric circles of the first set of lines; and

a plurality of radio-opaque labels on the sterile surgical drape, wherein each radio-opaque label of the plurality of radio-opaque labels is located at one intersection of the plurality of intersections in the radio-opaque pattern to provide a plurality of labeled intersections on the sterile surgical drape; and

directing imaging radiation at the patient and through the sterile surgical drape, wherein an image is obtained that includes a pattern image corresponding to the radio-opaque pattern on the surgical drape, the pattern image comprising a plurality of label images corresponding to the radio-opaque labels on the sterile surgical drape.

63. (Previously Presented) A method according to claim 62, wherein adhering the surgical drape comprises locating the surgical drape on a breast of the patient, wherein the central cutout is located over a nipple on the breast.

64. (Previously Presented) A method of medical imaging comprising:

applying a sterile surgical drape to a patient by unrolling a cylindrical portion of the sterile surgical drape onto an extremity, finger or other appendage of the patient, wherein the surgical drape comprises:

a radio-lucent sheet forming the cylindrical portion of the surgical drape; and

a radio-opaque pattern on the sterile surgical drape, wherein the radio-opaque pattern comprises a plurality of intersections, and a plurality of radio-opaque labels on the sterile surgical drape, wherein each radio-opaque label of the plurality of radio-opaque labels is located at one intersection of the plurality of intersections in the radio-opaque pattern to provide a plurality of labeled intersections on the sterile surgical drape;

directing imaging radiation at the patient and through the sterile surgical drape, wherein an image is obtained that includes a pattern image corresponding to the radio-



opaque pattern on the sterile surgical drape, the pattern image comprising a plurality of label images corresponding to the radio-opaque labels on the sterile surgical drape.

65. (Previously Presented) A method according to claim 64, wherein applying the surgical drape comprises stretching the radio-opaque sheet.

66. (Previously Presented) A method according to claim 64, wherein the surgical drape further comprises adhesive on an inner surface of the cylindrical portion, wherein applying the surgical drape comprises adhering the surgical drape to the patient.

67. (Previously Presented) A surgical drape according to claim 53, wherein some intersections of the plurality of intersections do not include one of the radio-opaque labels.

68. (Previously Presented) A sterile surgical drape comprising:  
a radio-lucent sheet comprising a central cutout and a slit extending outward from the central cutout;  
adhesive on a major surface of the radio-lucent sheet;  
a radio-opaque pattern on the sterile surgical drape, wherein the radio-opaque pattern comprises a perimeter, an interior within the perimeter, and a plurality of intersections distributed within the interior of the radio-opaque pattern, and wherein the radio-opaque pattern comprises a first set of lines and a second set of intersecting lines, wherein the first set of lines and the second set of intersecting lines form a plurality of intersections and further wherein the lines in the first set of lines are concentric circles and the lines in the second set of lines are radially oriented with respect to the concentric circles of the first set of lines; and  
a plurality of unique radio-opaque labels on the surgical drape, wherein each radio-opaque label of the plurality of unique radio-opaque labels is located at one intersection of the plurality of intersections in the radio-opaque pattern, and wherein a plurality of uniquely labeled intersections are provided in the interior of the radio-opaque pattern on the sterile surgical drape.

69. (Previously Presented) A surgical drape according to claim 68, wherein every intersection of the plurality of intersections comprises one of the radio-opaque labels such that one radio-opaque label of the plurality of unique radio-opaque labels is located at every intersection of the plurality of intersections.

70. (Previously Presented) A surgical drape according to claim 68, wherein some intersections of the plurality of intersections do not include one of the unique radio-opaque labels.

71. (Previously Presented) A sterile surgical drape comprising:  
a radio-lucent sheet;  
adhesive on a major surface of the radio-lucent sheet; and  
a radio-opaque pattern on the sterile surgical drape, wherein the radio-opaque pattern comprises a plurality of radio-opaque lines and a plurality of unique radio-opaque labels on the sterile surgical drape, wherein at least one line of the plurality of radio-opaque lines comprises a series of discrete shapes.

72. (Previously Presented) A surgical drape according to claim 71, wherein the series of discrete shapes comprises a series of line segments.

72. (Previously Presented) A surgical drape according to claim 71, wherein the series of discrete shapes comprises a series of discrete intersecting line segments.

73. (Previously Presented) A surgical drape according to claim 72, wherein the discrete intersecting lines segments intersect at substantially right angles.

74. (Previously Presented) A surgical drape according to claim 71, wherein the radio-opaque pattern comprises a perimeter and an interior within the perimeter, wherein at least some of the discrete shapes are located within the interior of the radio-opaque pattern;

and wherein the plurality of radio-opaque labels comprises a plurality of unique radio-opaque labels on the surgical drape, wherein each radio-opaque label of the plurality of unique radio-opaque labels is located proximate one of the discrete shapes

in the radio-opaque pattern, wherein at least some of the discrete shapes and the unique radio-opaque labels located proximate thereto are provided in the interior of the radio-opaque pattern.

75. (Previously Presented) A surgical drape according to claim 74, wherein one of the unique radio-opaque labels is located proximate every discrete shape of the series of discrete shapes in the at least one line of the radio-opaque pattern.

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**EVIDENCE APPENDIX**

None.

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**RELATED PROCEEDINGS APPENDIX**

None.